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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/557,196	04/12/2006	**Palaniswamy Sunder Raj**	687-140	5509

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EXAMINER	
BAEK, BONG-SOOK	
ART UNIT	**PAPER NUMBER**
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06/20/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/557,196	RAJ ET AL.	
	Examiner	Art Unit	
	BONG-SOOK BAEK	4161	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-59* is/are pending in the application.

4a) Of the above claim(s) *8-13,15,28-31,34-41,45,46 and 59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,14,16-27,32,33,42-44 and 47-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/17/2005, 1/24/2007, and 3/14/2007* .
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-59 are currently pending.

Election/Restrictions

Applicants' election of group I drawn to a composition and election of the following species: (1) enabling an individual to wake refreshed after sleeping; (2) Ibuprofen; (3) Oral administration and tablet formulation; (4) Saccharide (diluent), croscarmellose (disintegrant), magnesium stearate (lubricant), hydroxymeth£1propyl cellulose (coating agent), in the reply filed on 5/28/2008 are acknowledged.

Claim 8-13, 15, 28-31, 34-41, 45-46, and 59 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group or species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/28/2008. Claims 1-7, 14, 16-27, 32-33, 42-44, and 47-58 are under examination in the instant office action.

Priority

The instant application is a 371 of PCT/GB04/02330 filed on 06/01/2004 and claims benefit of foreign application filed on 05/30/2003. Acknowledgment is made of applicant's

claim for foreign priority under 35 U.S.C. 119(a)-(d). A certified copy of foreign application has been submitted on 11/17/2005.

The earliest effective U.S. filing date afforded the instantly claimed invention has been determined to be 06/01/2004.

Information Disclosure Statement

The information disclosure statements have been filed on 11/17/2005, 1/24/2007, and 3/14/2007. Since the IDS filed on 1/24/2007 includes all the references cited in the previous IDS filed on 11/17/2005, the IDS filed on 11/17/2005 has not been considered.

Claim objections

Claims 3 and 4 are objected to under 37 CFR 1.75 as being a substantial duplicate of claim 2. When two or more claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 50 are objected because of the following informalities: typographical errors. The term "sacaharide" should be corrected to --saccharide-- and "of" should be added between weight and saccharide in line 3 of claim 50. In addition, the same typographical errors and other misspellings should be corrected in the specification.

Claim Rejections - 35 USC § 112– Second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 22 and 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 recites the limitations "said pack" in line 2 of claim 22. There is a lack of antecedent basis for this limitation in the claim because claim 1 does not utilize the language of the limitation "said pack".

Claim 27 recites the limitations "said dosage" in line 2 of claim 27. There is a lack of antecedent basis for this limitation in the claim because claim 1 does not utilize the language of the limitation "said dosage".

Claims 42-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 42-44 are dependent on claim 1, but they do start with "The". Dependent claims should begin with the word "The" so that their dependent status is clear.

Claims 1-7, 17-27, 42-44, and 47-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-7, 17-27 and 42-58 are drawn to the use of a composition comprising triprolidine in combination with at least one further active pharmaceutical agent. Since the claim does not set forth any steps involved in the

method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1-7, 17-27, 42-44, and 47-58 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). Applicant was required to cancel or amend the use claims to be either product or process claims in accordance with group I, II, or III in the previous office action sent on 4/29/2008. However, applicant did not amend the use claims as required. Therefore, the claims 1-7, 17-27, 42-44, and 47-58 are withdrawn from further examination and only claims 14, 16, 32-33 are under further examination in the instant office action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 14, 16, and 32-33 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,025,019 (Issue Date: 6/18/1991).

The instant invention is drawn to a waking refreshed aid or a pharmaceutical formulation for enabling an individual to wake refreshed comprising triprolidine or a salt or hydrate thereof in combination with at least one further active pharmaceutical agent (elected species: ibuprofen) in association with a pharmaceutically acceptable carrier therefor and instructions for administration thereof at or just before the desired sleeping time. The instant invention is further drawn to the waking refreshed aid wherein the instructions for administration instruct a single dose of the triprolidine active ingredient of up to 20 mg, preferably between 0.01 and 20 mg prior to sleep time (claims 32-33).

US Patent 5,025,019 disclose a composition a non-steroidal anti-inflammatory drug including ibuprofen and in combination with at least one other active component selected from a decongestant, cough suppressant, expectorant or antihistamine including triprolidine for the relief of cough, cold and cold-like symptom (abstract and claim 1). US Patent 5,025,019 further teaches that the usual single dosage of triprolidine (HCL) is 1.25-2.5 mg (Table I, 3rd example), which falls within the claimed range in the instant claims 32-33 and the pharmaceutical composition will be administered in admixture with suitable pharmaceutical diluents, excipients or carriers (column 5, lines 57-66).

Since the instant invention is directed to a composition, an intended use, which is enabling an individual wake refreshed, does not have a patentable weight. In accordance with the

patent statutes, an article or composition of matter, in order to patentable, must not only be useful and involve invention, but must also be new. If there is no novelty in an article or composition itself, then a patent cannot be properly granted on the article or composition, regardless of the use for which it is intended. The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statutes make no provision for patenting of an article or composition which is not, in and of itself, new.

With regards to the instruction, the printed matter on a label or package insert of a kit or container does not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture since there is no functional relationship between the label or package insert of a kit and the product, composition, or article of manufacture of a kit or container. See *In re Haller* 73 USPQ 403 (CCPA 1947), where it is held that application of printed matter to old article cannot render the article patentable. In the opinion text of In re Haller, it is stated that: Whether the statement of intended use appears merely in the claim or in label on the product is immaterial so far as the question of patentability is concerned.

Also see *In re Venezia* 189 USPQ 49 (CCPA 1976), where kits are drawn to the structural attributes of interrelated component parts and not to activities that may or may not occur. Further, *In re Miller* 164 USPQ 46 (CCPA 1969) and *In re Gulak* (CAFC) 217 USPQ 401 relate to a mathematical device and to a measuring cup respectively as well as *In re Ngai*, 70 USPQ2d 1862 (CAFC 2004). In each of these cases, the printed matter is considered a patentable distinction because the function of the device depends upon the printed matter itself, which is a patentable distinction because the function of the device depends upon the printed matter itself, which is a part of the substrate; without the printed indicia or numbers, the substrates lose their

function. Such is not the case with the instantly claimed articles or kits. The claimed articles of the kit remain fully functional absent the labeling or printed instructions for use. Thus the instructions for use included in a kit or article manufacture constitute an "intended use" for that kit or article of manufacture. Intended use does not impart patentable weight to a product. See MPEP 2111.03: Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963).

In the instant case, the kit claims are drawn to an old article or composition, which further comprises labeling instructions. The intended use, which is recited on the label or package of the insert, lacks a function relationship because the insert or label does not physically or chemically affect the chemical nature within the article of manufacture, and furthermore, the old article or old composition of the kit can still be used by the skilled artisan for other purposes. Therefore the old article or composition which are comprised with the claimed kit are unpatentable over the prior art, because they function equally effectively with or without the labeling, and accordingly no functional relationship exists between the instructions for use and the composition.

Thus the claims are addressed as being drawn to an article comprising an old composition of a kit and a package insert, the instructions on the insert bearing no patentable weight with

regard to double patenting, 102 and 103 rejections. As such, the instant claims are anticipated by US patent 5,025,019.

2) Claims 14, 16, and 32-33 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent Application Publication 2002/0058642 (Pub. Date: 5/16/2002).

US 2002/0058642 disclose a composition comprising glucosamine, analgesic including ibuprofen in combination with one or more other pharmaceutical active component including triprolidine for the treatment of such ailment as allergies, sleep disorder, cough, colds, and/or flu symptoms, and arthritic and joint pain (p3, [0019]). US 2002/0058642 further teaches that the pharmaceutical composition can be prepared in admixture with a pharmaceutical carrier (p3, [0020]).

The instant composition comprises at least one further active pharmaceutical agent in combination with triprolidine, therefore the composition can include more than one further active pharmaceutical agent like glucosamine. The instant invention is directed to a composition. The dose or administration limitation does not limit the composition and does not get patentable weight. The dosing and administration is reasonably interpreted as taking a portion of the claimed composition for administration but such portioning does not limit what is actually being claimed. Also, an intended use, which is enabling an individual wake refreshed, does not have a patentable weight as stated before. With regards to the instruction, the printed matter on a label or package insert of a kit or container does not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture since there is no functional relationship between the label or package insert of a kit and the product, composition, or article of

manufacture of a kit or container as stated before. As such, the instant claims are anticipated by US 2002/0058642.

Provisional Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 14, 16, and 32-33 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 48 and 57 of copending Application No. 10/448,455. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the '455 application claims and the instant claims encompass a composition comprising triprolidine or a salt or hydrate thereof in combination with at least one further active pharmaceutical agent for enabling an individual to wake refreshed since having a instruction or a dosage limitation bears no patentable weight with regard to double patenting, 102 and 103 rejections as stated above.

This is a provisional obviousness-type double patenting rejection.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BONG-SOOK BAEK whose telephone number is 571-270-5863. The examiner can normally be reached 8:00-5:00 Monday-Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on 571-272-0847. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BONG-SOOK BAEK
Examiner, Art Unit 4161

Bbs

/Patrick J. Nolan/

Supervisory Patent Examiner, Art Unit 4161